

## REMARKS

Claims 9 and 17 are pending in the present application.

New claim 17 is directed to a pharmaceutical composition comprising the peptide of claim 9. Support for this claim can be found in the specification, at page 4, lines 25-30. Claim 17 reads on the elected invention. No new matter is added by this claim.

### **Objections to the Specification.**

The specification has been objected to for not including an abstract. In response, the specification has been amended to add an abstract commensurate with the present claims. No new matter is added by this amendment.

The Office Action also indicates that the specification includes numerous amino acid sequences that are not identified by a sequence identifier number (SEQ ID NO). Applicants respectfully draw the Examiner's attention to the Preliminary Amendment dated December 16, 2005, which was submitted upon entry into the National Stage, and which extensively amended the specification to add the SEQ ID NOs to the specification. Applicants have reviewed the specification in light of the Preliminary Amendment, and do not find any instances where sequence identifiers are still missing.

The Office Action also indicated that the benefit statement on page 1 of the application should include the foreign priority information. In response, Applicants submit that foreign and domestic priority benefit requirements have been complied with in this application. A statement indicating that this application is the National Stage of International Application No. PCT/EP2004/006943, filed on June 25, 2004, was included in the specification by Preliminary Amendment upon entry into the National Stage. This statement is in accordance with 37 C.F.R. 1.78, as well as the guidance provided in the Official Gazette Notice entitled "Claiming the Benefit of Prior-Filed Application under 35 U.S.C. 119 (e), 120, 121, and 365(c)" dated March 18, 2003. Foreign priority to European Application EP 0314332.5 was claimed in the Declaration submitted upon entry into the National Stage, in accordance with 37 C.F.R. 1.63(c)(2). See M.P.E.P. 201.13, section II(A). Applicants are not aware of any requirement to include a foreign priority statement in the specification. Clarification is requested.

**Rejections Under 35 U.S.C. §101.**

Claim 9 stands rejected under 35 U.S.C. §101 as allegedly not being directed to patentable subject matter, since the claim did not specify that the claimed peptide is an isolated peptide. In response, the preamble of claim 9 has been amended to refer to "an isolated peptide".

**Rejections Under the Second Paragraph of 35 U.S.C. §112.**

Claim 9 stands rejected under 35 U.S.C. §112 as being indefinite, since the sequence shown in the claim and identified as SEQ ID NO: 1 differs from the version of SEQ ID NO: 1 set forth in the Sequence Listing. In particular, SEQ ID NO: 1 in the original Sequence Listing included an alanine residue at the N-terminus that is not found in the sequence shown in the claim or in the specification. In response, Applicants have submitted herewith a Replacement Sequence Listing (paper copy and Computer Readable Form), which corrects this inadvertent error by deleting the initial alanine residue from SEQ ID NO: 1. Support for this amendment can be found in the sequence shown on page 4, line 21. No new matter is added by this amendment.

**Rejections Under 35 U.S.C. §102.**

Claim 9 stands rejected under 35 U.S.C. §102 as allegedly being anticipated by Scharf *et al.* This rejection is unwarranted. Claim 9, as originally presented, and as amended in the Preliminary Amendment dated December 16, 2005, is directed to an immunogenic portion of hirudin, and does not encompass a full length hirudin molecule, as disclosed in the reference. To clarify this point, claim 9 has been amended to replace the transitional phrase "having" with the closed transitional phrase "consisting of" and to clarify that the peptide consists of SEQ ID NO: 1 or a portion of SEQ ID NO: 1 consisting of at least 9 consecutive amino acid residues thereof. According to the Office Action, the full-length hirudin proteins disclosed by Scharf *et al.* are peptides consisting of at least 9 consecutive amino acid residues of SEQ ID NO: 1, as claimed. This characterization is unwarranted. Present claim 9 uses the closed transitional phrase "consisting of" in describing the claimed peptides. The full-length hirudin compounds disclosed by Scharf *et al.* include residues that are not within the metes and bounds of SEQ ID NO: 1. Since the reference does not single-out or specifically refer to SEQ ID NO: 1 or any portions of SEQ ID NO: 1 having a length of at least 9 amino acid residues, the present claims are not anticipated by Scharf *et al.* The same reasoning applies to

the patentability of new claim 17, as well, which includes all of the limitations of claim 9.

Withdrawal of the rejection is requested.

**Rejections Under 35 U.S.C. §103.**

Claim 9 stands rejected under 35 U.S.C. §103 as allegedly being obvious over Scharf *et al.* This rejection is unwarranted as well. The disclosures of full length hirudin molecules would not have rendered the presently claimed peptides obvious to one of ordinary skill in the art, since the reference does not teach or even suggest the immunogenic nature of the claimed peptides, which consist of particular portions of hirudin. There is no teaching or suggestion in the reference that would have directed one of ordinary skill in the art to isolate or prepare the particularly claimed immunogenic peptides. The reference is silent regarding immunogenicity and regarding the claimed portions of the hirudin molecule. Withdrawal of this rejection is also warranted.

**Conclusion.**

Reconsideration, allowance of the claims, and early passing of this application to issue is solicited.

Respectfully submitted,

Dated

23 July 2007

By

Talivaldis Cepuritis  
Talivaldis Cepuritis (Reg. No. 20,818)

OLSON & HIERL, LTD.  
20 North Wacker Drive, 36th Floor  
Chicago, Illinois 60606  
(312) 580-1180